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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/784,393 | 02/23/2004 | Aaron T. Timperman | 22085/2112 | 8432 |

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PALMER & DODGE, LLP
PAULA CAMPBELL EVANS
111 HUNTINGTON AVENUE
BOSTON, MA 02199

EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--------------------------------------------|--|
| Office Action Summary | Application No. 10/784,393 | Applicant(s) TIMPERMAN, AARON T. | |
| | Examiner William H. Beisner | Art Unit 1744 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2004 and 15 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 13-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/15/04&8/2/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-12, in the reply filed on 10/8/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 13-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/8/04.

Information Disclosure Statement

3. The information disclosure statements filed 8/2/04 and 11/15/04 have been considered and made of record.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 6,007,690) in view of Wang et al.(Rapid Communications in Mass Spectrometry).

The reference of Nelson et al. discloses a microfluidic device that includes an inlet channel (66); a reaction channel (enrichment channel, 62) and solid supports (3) in communication with the reaction channel and capable of concentrating a charged analyte produced by a reaction in the reaction channel.

While the reference of Nelson et al. discloses that the reaction channel (enrichment channel, 62) may be used as a microreactor for protein digestion (See column 4, lines 43-67), the reference does not specifically disclose that enzyme is located in the channel.

The reference of Wang et al. clearly discloses that it is conventional in the art to provide enzyme within a reaction channel on a microfluidic device (See Figure1 and related disclosure).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the enrichment channel (62) of the reference of Nelson et al. with an enzyme for the known and expected result of providing an art recognized means for protein digestion so as to provide a microreactor as suggested by the reference of Nelson et al.

With respect to the specifics of the membrane employed of claims 2-4, the reference of Nelson et al. discloses a number of possible solid supports that can be employed with respect to the enrichment channel (See column 6, lines 1-56). As a result, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the optimum material for enclosing the enrichment channel based merely on the specifics of the analyte to be reacted and/or detected in the system.

With respect to the charge on the membrane of claims 5-10, based merely on the specific material of the membrane employed, the material will inherently include a positive or negative charge. Additionally, it would have been obvious to one of ordinary skill in the art to provide a desired charge for the capture of reaction products as suggested by the reference of Nelson et al. (See column 6, lines 46-53).

With respect to the side channels of claims 6-10, the reference of Nelson et al. discloses the use of side channels (14, 15).

With respect to the electrodes of claims 9 and 10, the reference of Nelson et al. discloses the use of electrodes (60 and 61) with respect to the side channels. As is known in the field of electrophoresis, the voltage applied to the electrodes can be positive or negative based merely on the desired direction of flow. As a result, the electrodes of Nelson et al. are structurally capable of being positive or negative.

With respect to the claimed upstream module of claim 11, it would have been obvious to one of ordinary skill in the art to purify the sample prior to introduction into the microreactor

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system for the known and expected result of removing any components of the sample which may interfere with the analysis reactions and/or detection.

With respect to the downstream separation module of claim 12, the reference of Wang et al. discloses that it is conventional in the art to provide the protein digested sample of a microfluid device to a MS for further separation and analysis (See Figure 1 and related text). As a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further analyze the reaction products of the device of Neslon et al. using a MS as suggested by the reference of Wang et al.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'William H. Beisner', with a long horizontal flourish extending to the right.

William H. Beisner

Primary Examiner

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WHB